

Applicant(s): S. Jayaraman
Application No.: 10/696,174
Examiner: S. Jackson

Remarks

Claims 1-2, 5-14, and 16-28 are presented for the Examiner's review and consideration. Claims 1, 2, 5, 6, 8, 12, 14, 17, 18, 20, and 23 have been amended, and claims 3, 4, and 15 have been canceled. Claims 26-28 have been added. Applicant believes the claim amendments, claim additions, and the accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

35 U.S.C. §102 Rejection

Claims 1-4 and 6-25 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Application Publication No. 20030060877 to Falotico *et al* (hereinafter "Falotico"). In response, Applicant respectfully submits that this rejection should be withdrawn.

Falotico discloses medical devices coated with therapeutic drugs to treat various vascular diseases, for example, restenosis and vulnerable plaque (abstract). Restenosis after percutaneous transluminal coronary angioplasty is a gradual process initiated by vascular injury. Multiple processes, including thrombosis, inflammation, growth factor and cytokine release, cell proliferation, cell migration and extracellular matrix synthesis each contribute to the restenosis process (¶0006). Atherosclerosis is another vascular disease which includes the hardening of the arteries with plaque. This inflamed plaque is known as atherosclerotic vulnerable plaque (¶0023). Given the lack of currently available effective technologies for detecting vulnerable plaque, the treatment of vulnerable plaque is typically initiated only after the plaque has ruptured and clinical symptoms have developed. Detection technologies currently under investigation include refined MRI, thermal sensors, elasticity sensors, intravascular ultrasound, optical coherence tomography, contrast agents, and near-infrared and infrared light. The treatment of vulnerable plaque, however, is preferably as described below (¶0198). Essentially, there are two physiologic processes ongoing in active vulnerable plaque: inflammation and lipid metabolism (¶0199). A stent may include one or more therapeutic agents for treating both the inflammation

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and lipid metabolism processes (§0200).

Applicant discloses, *inter alia*, devices and methods for treating a vascular disease (abstract). To treat or prevent a specific disease process of a vascular disease, the disease process or processes which are prevalent in the vessel wall of the patient are identified (§0093). Techniques used to identify these events or processes include an angiogram, fluoroscopy, CT scan, MRI, intravascular MRI, lesion temperature, genetic determination, etc. (§0086). Construction of a disease specific therapeutic coating can be designed which can be used to treat or prevent processes of restenosis from people with various risk factors and underlying mechanisms. That is, restenosis is different in every individual depending on the underlying conditions that constitute the vascular disease (§0092). A therapeutic agent is selected for treating or preventing the identified disease process or processes. An intravascular implant may be coated with a therapeutically effective amount of the therapeutic agent to treat or prevent the disease process (§0093).

Applicant respectfully contends that Falotico fails to teach or suggest all the elements of the claimed invention. For example, Falotico does not teach the identification of a specific disease process of a vascular disease within a specific patient. Rather, Falotico simply lists various disease processes of certain vascular disease, like restenosis and atherosclerosis. Therefore, Falotico does not select therapeutic agents based on an existing disease process nor does he tailor his medical implant to a specific disease process prevalent in a particular patient. In contrast, Applicant teaches the identification of a disease process in a patient and the selection of a therapeutic agent to specifically treat that disease process. Applicant's implant is tailored to the underlying conditions in an individual patient.

To highlight this distinction, Applicant has amended independent claims 1, 17, and 23 to include, *inter alia*, the identification of an existing disease process within a patient. Applicant respectfully submits that these independent claims are patentable over Falotico. Based on at least their dependencies, Applicant submits that claims 2, 6-14, 16, 18-22, and 24-25 are patentable as well.

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35 U.S.C. §103 Rejection

Claim 4 (or claim 5) was rejected under 35 U.S.C. §103(a) as being unpatentable over Falotico in view of U.S. Patent No. 6,273,913 to Wright *et al* (hereinafter "Wright"). Applicant respectfully submits that this rejection is moot based on the claim amendments discussed above.

New Claims

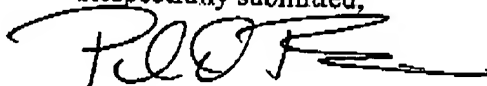
Applicant has added claims 26-28 to the application. Support for these claims may be found through out the specification with emphasis on ¶0094.

Conclusion

In light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

No fee is believed to be due with this submission. However, please charge the required fee (or credit overpayments) to the Deposit Account of the undersigned, Account No. 500601 (Docket No. 795-A03-004).

Respectfully submitted,



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